

PATENT COOPERATION TREATY



Translation

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference VCstsF004/79	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/FR2003/003154	International filing date ( <i>day/month/year</i> ) 24 octobre 2003 (24.10.2003)	Priority date ( <i>day/month/year</i> ) 30 octobre 2002 (30.10.2002)
International Patent Classification (IPC) or national classification and IPC C07K 14/20		
Applicant VIRBAC		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>3</u> sheets.</p>	
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>	

Date of submission of the demand 03 mai 2004 (03.05.2004)	Date of completion of this report 18 February 2005 (18.02.2005)
Name and mailing address of the IPEA/EP	Authorized officer
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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/FR2003/003154

## I. Basis of the report

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

☐ the international application as originally filed.

☒ the description, pages 1-45, as originally filed,  
pages \_\_\_\_\_, filed with the demand,  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

☒ the claims, Nos. 1-25, as originally filed,  
Nos. \_\_\_\_\_, as amended under Article 19,  
Nos. \_\_\_\_\_, filed with the demand,  
Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

☒ the drawings, sheets/fig 1/13-13/13, as originally filed,  
sheets/fig \_\_\_\_\_, filed with the demand,  
sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

2. The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/fig \_\_\_\_\_

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/FR 03/03154

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-5	YES
	Claims	6-25	NO
Inventive step (IS)	Claims		YES
	Claims	1-25	NO
Industrial applicability (IA)	Claims	1-25	YES
	Claims		NO

**2. Citations and explanations****1. Reference is made to the following documents:**

D1: WO 01/59123 A (BRANGER CHRISTINE; ENVT TOULOUSE (FR); VIRBAC (FR); ANDRE FONTAINE) 16 August 2001 (2001-08-16)

D2: WO 99/42478 A (UNIV CALIFORNIA) 26 August 1999 (1999-08-26)

D3: WO 96/36355 A (UNIV CALIFORNIA) 21 November 1996 (1996-11-21)

**2. The present application does not meet the requirements of PCT Article 33(1), since the subject matter of claims 1-25 does not comply with the criterion of novelty (PCT Article 33(2)).**

Document D1 describes the leptospire PPL protein, fragments and variants of said protein and immunogenic peptides derived therefrom (alone or in larger molecules or bound to carriers), capable of inducing effective immune protection against one or more pathogenic leptospire serovars (pages 6 and 7, claims). D1 also describes the 6E5A4F2 antibody,

used for passive immunisation (page 39; claims), that recognises the peptides of SEQ ID No 1 according to the present application (cf. page 17 of the present application).

Therefore, document D1 anticipates all the features of the subject matter of claim 6, which is directed to a protein consisting of a peptide of SEQ ID No 1 coupled to a carrier protein. Contrary to the applicant's arguments, the feature "coupled to a carrier protein" does not establish the novelty of the subject matter of claim 6 over the proteins known from D1, including SEQ ID No 1.

3. The present application does not meet the requirements of PCT Article 33(1), since the subject matter of claims 1-5 does not involve an inventive step (PCT Article 33(3)).

The subject matter of claims 1-5 relates to peptides derived from the leptospire PPL protein and comprising 15 to 100 amino acids.

The problem that the present invention is intended to solve can therefore be considered to be that of providing alternative peptides derived from PPL, capable of inducing protection against leptospirae.

The solution proposed in claims 1-5 of the present application is not considered inventive (PCT Article 33(3)) for the following reasons:

The subject matter of the claims of the present application includes a plurality of peptides that have not been shown and do not credibly appear to

provide a solution to said problem, which is a precondition for recognising an inventive step.

Moreover, starting with D1, a person skilled in the art was aware of the immunogenic property of the whole PPL protein and would have been led to develop short immunogenic PPL fragments. In addition, an antibody against a PPL epitope, capable of inducing passive immunisation and of being used to select immunogenic fragments, was available to such a person, who would therefore have solved the problem and arrived at the claimed solution without an inventive step being involved.

The applicant mentions surprising effects of the peptide according to the invention in order to justify an inventive step. However, these surprising effects, insofar as they can be supported by comparative tests, only appear to concern the peptide of SEQ ID No 1, whereas the extent of protection of claims 1-5 is much wider.